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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,481	06/23/2003	Andrew Fensome	AHPWA25AUSA	8944

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,481	Applicant(s) FENSOME ET AL.	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 5, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7 and 27-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 27-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

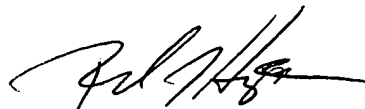
Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.



Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/10/05</u> → <u>8/24/05</u> | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1-7, 25 AND 27-40 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed August 1, 2005 and Third Supplemental Information Disclosure Statement filed August 20, 2005 have been received and entered into the application. Accordingly, claims 1-3, 7, 25, 27-31 and 34-40 have been amended and claims 8-11, 14 and 26 have been canceled. Also, as reflected by the attached, completed copy of form PTO/SB/08A&B, the cited references have been considered.

In view of the above referenced amendments, the rejection of claims 35-40 under U.S.C. 112, first paragraph is withdrawn.

Also, because claims 91 and 92 of U.S. Patent No. 6,436,929 (Zhang et al.) require Q¹ to be either NR⁷ or CR⁹, while in Applicant's claims 1-7, 25 and 27-34, previously claims 1-11, 14 and 25-36, compound II required Q to be S, the double patenting rejection set forth in the previous Office action is also withdrawn.

Allowable Claim

In light of the above referenced amendment, claim 37 stands in condition for allowance.

Claim Objection, (NEW)

In view of the above referenced amendments, claims 35, 36 and 38-40 are deemed objectionable.

Claims 35, 36 and 40 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

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In claim 38, "said selective estrogen receptor modulator", (penultimate line), has no antecedent basis. This objection may be overcome by amending the expression "and an estrogen", (4th line from the end of the claim), to ---a selective estrogen receptor modulator---.

Claim 39 is objected to because the language employed therein is cumbersome. The last section "(c)" should be amended as follows in order to overcome the present objection:

"(c) a third phase of an orally and pharmaceutically placebo being administered for 1 to 10 days ~~in which~~ excluding the days on which phase (a) or (b) occurs ~~is not administered 1 to 10 days.~~".

Claim Rejection - 35 USC § 103

Claims 1-7, 25 and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/66570 and applicants' acknowledgment at page 4, lines 3-5 of the present specification in view of Gast et al. (U.S. Patent Application Publication No. 2002/0061875), each of record, for the reasons of record as set forth in the previous Office action dated April 1, 2005, as applied to claims 1-11, 14 and 25-36.

Applicants' arguments/remarks at pages 29-30 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

In particular, Applicants have urged that "While certain compounds of the present invention, as exemplified by the compound of formula II in claim 1, may be dominated by the '570 [reference], '[t]he fact that that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness" (response at page 29, middle of the page).

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In response, the Examiner believes that the subgenus of compounds disclosed in the '570 reference at pages 7-19 reference is sufficiently small and particularly disclosed so as to have rendered obvious the presently claimed compounds. The Examiner is guided in his finding by the MPEP at § 2144.08 (II) (b) "CONSIDER THE EXPRESS TEACHINGS"

"If the prior art reference expressly teaches a particular reason to select the claimed species or subgenus, Office personnel should point out the express disclosure which would have motivated one of ordinary skill in the art to select the claimed invention. An express teaching may be based on a statement in the prior art reference such as an art recognized equivalence. For example, see *Merck & Co. v. Biocraft Labs.*, 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989) (holding claims directed to diuretic compositions comprising a specific mixture of amiloride and hydrochlorothiazide were obvious over a prior art reference expressly teaching that amiloride was a pyrazinoylguanidine which could be coadministered with potassium excreting diuretic agents, including hydrochlorothiazide which was a named example, to produce a diuretic with desirable sodium and potassium eliminating properties). See also, *In re Kemps*, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1312 (Fed. Cir. 1996) (holding there is sufficient motivation to combine teachings of prior art to achieve claimed invention where one reference specifically refers to the other)"

Here, the substituents for Applicants' compounds are preferred which would have motivated the skilled artisan to select such substituents and make and use the present compounds. Also, the substituents do not differ greatly from one another and as just as complex as the claimed species.

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MPEP § 2131.02, under the heading "A Reference that Clearly Names the Claimed Species Anticipates the Claim No Matter How Many Other Species are named", states:

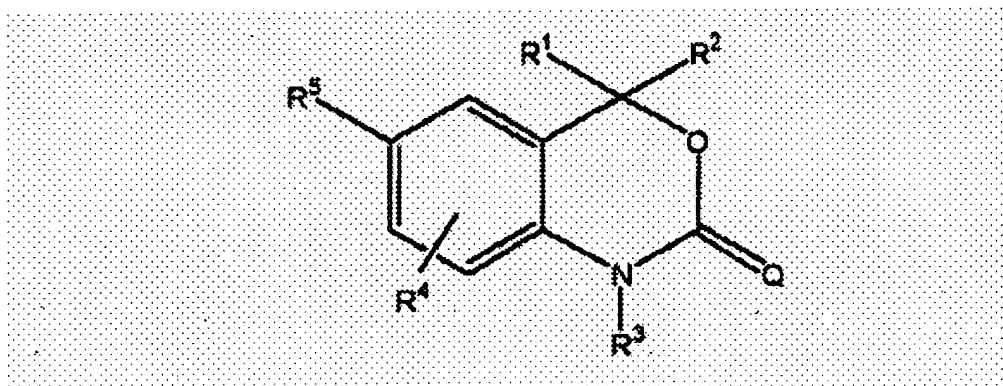
A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that "the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. § 102(a), in that publication."). Id. at 1718. See also In re Sivaramakrishnan, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982).

In the current situation, anticipation is not an issue. However, the above is germane to the present matter. In particular, by replacing "The Merck Index" with "the '570 reference" and the claimed substituents with those substituents clearly named in the '570 reference, the Examiner is of the opinion that each and every one of the substituents disclosed in the '570 reference is clearly described and direction is given in the '570 reference for using each and every one of the disclosed substituents in a manner such that the presently claimed compounds would have clearly been obvious to one of ordinary skill in the art.

For example, where in the formula at the top of page 7, on the left, of the '570 reference at page where (i) R¹ and R² may be "H or C₁ to C₆ alkyl or may be fused to form a spirocyclic

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ring; (ii) R^3 is H (page 8 of '570, line 1); (iii) R^4 is H (page 8, line 7 of the '570 reference); and (iv) R^5 may be a five or six membered heterocyclic ring with 1 ring atom such a NR as defined in the present claims may be found in the '570 reference at page 8, line 10 – page 9, line 8, i.e., R^6 is H or C_1 to C_3 alkyl. Also, the present definition of the substituents of the compound of formula II may be found in the '570 reference at page 10 "Among the preferred compounds of this invention" (emphasis added), wherein in the general formula of:



R^1 is H, C_1 to C_6 alkyl (line 12), R^2 is H, C_1 to C_6 alkyl (line 15), or R^1 and R^2 are fused to from a) a 3 to 8 membered spirocyclic alkyl ring. Also, at page 9, line 14, page 12, line 9 and page 15 line 20, " Q^1 ", (corresponding to Applicants' " Q ") is taught as being preferred and most preferred as " S ", i.e., sulfur. Further, at page 8, line 27; page 12, line 6, page 13, line 20 and page 15, line 17, the 5 member heterocyclic ring (which corresponds to the ring attached at R^5 on Applicants' structure), may have substituted therein by an NH moiety, i.e., a pyrrole moiety, which itself may have a cyano, (CN), substituent attached thereto, e.g. see page 17, line 8 for substituent " X " on a "Preferred subgroup of this invention."

Also, Applicants' should remember that while the '570 reference is comprehensive, such does not diminish it from serving as a basis for obviousness (see above discussion relating to MPEP § 2131.02 and "the Merck Index").

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Applicants have also briefly stated that "In fact, the inventors found that the compounds exemplified by compounds of formula II have unexpected potency" (Applicants' response at page 30, penultimate line of the last full paragraph). Such statement is covered in the MPEP § 2145. Applicants have not identified and explained the comparative data which would lead one to conclude the conclusion urged. Such would have to include a showing of a sufficient number of compounds that that is representative of the claimed genus and a comparison against a sufficient number of compounds from the '570 reference. Further, it should be stated what one skilled in the art would have expected from such a comparison. Also, a statistical analysis must be performed in order to determine whether the results reported are not due to chance alone.

Taken the above comments together with those comments already of record, the Examiner is compelled to maintain that claims 1-7, 25 and 27-34 remain properly rejected.

The Examiner has pointed to page and line of the references relied on to support the conclusion that the presently claimed subject matter would have been obvious.

Accordingly, the claims are deemed properly rejected.

Double Patenting Rejection Withdrawn

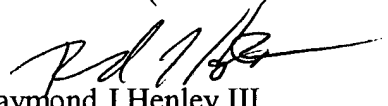
U.S. Patent No. 6,436,929, *inter alia*, no longer serves as a basis for a double patenting rejection because in claims 91 and 92, based on the present amendment, Q cannot be S as required in the present claims, e.g., claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

October 6, 2005